

**REMARKS**

***Status of the Claims***

Claims 1, 2, 4-8, 10-15 and 17-26 are in the application.

Claims 1, 2, 4-8, 10-15 and 17-26 are rejected.

By way of this amendment, claims 7 and 15 have been amended, and new claims 27-32 have been added.

Upon entry of this amendment, claims 1, 2, 4-8, 10-15 and 17-32 will be pending.

***Summary of the Amendment***

Claims 7 and 15 have been amended to delete reference to Ox40 ligand.

New claims 27-29 correspond to claims 22-24, respectively, but with a deletion of the reference to functional fragments.

New claims 30-32 correspond to claims 1, 7 and 15, respectively, but with a deletion of the reference to functional fragments.

No new matter has been added.

***Claim Rejections – 35 USC § 102***

**O'Hare**

Claims 1-2, 4-5, 13 and 22 remain rejected under 35 U.S.C. 102 (b) as being anticipated by US Patent No. 6,017,735A to O'Hare et al. It is asserted that the disclosure by O'Hare et al. still encompass the rejected claims 1-2, 4-5, 13, 22 and 25. It is asserted that a reasonable interpretation of the broadest scope of claims 1-2, 4-5, 13 and 22 could read on a fusion protein as disclosed in O'Hara because, it is asserted, the claim does not exclude the possibility that a coding sequence for a fusion protein may be included on the same molecule. Moreover, it is asserted that O'Hara also discloses embodiments in which a single nucleic acid molecule that encodes VP22 and Ox40 connected by a linker encodes the connected proteins which are subsequently cleaved. These reasons are wholly without merit and the rejections should be withdrawn.

O'Hare discloses coupled proteins such as fusion proteins, and nucleic acid constructs encoding them, including a coupled protein that comprises HSV VP22 protein and an immunomodulating protein such as OX40. According to O'Hare, the VP22 portion of the coupled protein has intercellular trafficking functions and facilitates distribution/delivery of the immunomodulating protein coupled to it. The proteins in O'Hare are necessarily coupled since the VP22 protein sequences are provided in order to help direct the immunomodulating proteins. O'Hare discloses coupled proteins which include a linker sequence that can be processed.

The claims are not anticipated by O'Hare. It is well established that to anticipate a claim, each and every element of the claim must be present in the reference, expressly or inherently. Claim 1 includes several features which are not disclosed by O'Hare

Claim 1 refers to a composition comprising two nucleic acid molecules. Claim 1 recites that one of the nucleic acid molecules comprises coding sequences for an immunogen and the other nucleic acid molecules comprises coding sequences for an Ox40 and the other listed immunomodulatory proteins.

O'Hare does not disclose a composition having one nucleic acid molecule that encodes an immunogen and a separate nucleic acid molecule that encodes Ox40 as set forth in claim 1. O'Hare teaches that the immunogen and Ox40 are expressed as a connected proteins which necessarily requires that the coding sequences for both the immunogen and Ox40 be linked as a single sequence. The claimed subject matter requires that the coding sequences be present on separate nucleic acid molecules while O'Hare requires that the coding sequences be linked and present on the same nucleic acid molecule.

The claimed invention is not disclosed in O'Hare expressly or inherently and so is not anticipated by O'Hare. To anticipate a claim, each element must be present in the reference. Each claimed element is not present in the O'Hare expressly or inherently. Therefore, O'Hare does not anticipate the claimed invention.

Applicants respectfully request that the rejection of claims 1-2, 4-5, 13 and 22 under 35 U.S.C. 102 (b) as being anticipated by US Patent No. 6,017,735A to O'Hare et al. be withdrawn.

**Emtage**

Claims 7-8, 10, 15, 17-19, 25-26 remain rejected under 35 U.S.C 102(e) as being anticipated by Emtage et al. (US2003/0113919A1). It is asserted that claims 7-8, 10, 15, 17-19, 25-26, still recite OX40L and therefore remain anticipated by Emtage.

Claims 7 and 15 have been amended to delete the recitation of Ox40 Ligand and thereby obviate the rejection. As amended, claims 7-8, 10, 15, 17-19, 25-26 are not anticipated by Emtage.

Applicants respectfully request that the rejection of claims 7-8, 10, 15, 17-19 and 25-26 under 35 U.S.C. 102 (e) as being anticipated by Emtage et al. (US2003/0113919A1) be withdrawn.

***Claim Rejections – 35 USC § 103***

Claims 7-8, 10-12, 15, 17-19 and 25-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Emtage et al. (US2003/0113919A1) in view of Clement et al. (J. Infect. Dis. 2002, 185, pp. 165-173). It is asserted that claims 7-8, 10, 15, 17-19, 25-26, still recite OX40L and therefore remain obvious over Emtage in view of Clement.

Claims 7 and 15 have been amended to delete the recitation of Ox40 Ligand and thereby obviate the rejection. As amended, claims 7-8, 10, 15, 17-19, 25-26 are not rendered obvious by Emtage in view of Clement.

Applicants respectfully request that the rejection of claims 7-8, 10, 15, 17-19 and 25-26 under 35 U.S.C. 103 (a) as being unpatentable over Emtage et al. (US2003/0113919A1) in view of Clement et al. (J. Infect. Dis. 2002, 185, pp. 165-173) be withdrawn.

***Priority***

The Office indicates that Applicants' claim for priority to an earlier filed application requires a specific reference to the prior filed application on the first page of the specification following the title. Applicants respectfully note that such a reference was added by preliminary

amendment filed with the application on December 13, 2005. Accordingly, Applicants are in compliance with 37 CFR 1.78(a).

***Informality Issues***

Applicants respectfully urge that the references to immunomodulatory proteins as set forth in claims 1, 7 and 15 are appropriate and that one skilled in the art would recognize the terminology.

***Claim Rejections – 35 USC § 112, second paragraph***

Claims 1-2, 4-8, 10-15, 17-25 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is asserted that claims 1, 7, 15, 22, 23 are vague and indefinite in that the metes and bounds of the cited “functional fragment thereof” are not defined. It is asserted that because the specification does not have the definition for the phrase, the metes and bounds of this term cannot be determined. Applicants respectfully disagree.

The specification includes a definition of “functional fragment” on page 7, lines 5-8 of the specification as filed. This definition recites

As used herein, "functional fragment" is meant to refer to a fragment of an immunomodulating protein that, when delivered in conjunction with an immunogen, provides an increased immune response compared to the immune that is induced when the immunogen is delivered without the fragment. Fragments are generally 10 or more amino acids in length.

One skilled in the art would readily understand this definition and how it is to be interpreted with respect to the meaning of functional fragments of proteins such as Ox40. One skilled in the art would clear recognize what is or is not a fragment of a protein such as Ox40. Moreover, one skilled in the art would clear recognize what is meant by increasing the immune response induced by an immunogen when co-delivered compared to the immune response to an

immunogen without co-delivery. The meaning of what is or is not a functional fragment is clear as are the claims that recite such an element. One skilled in the art can readily recognize what is meant to be within or outside the scope of the claim. The requirements of the second paragraph of section 112 are satisfied.

The metes and bounds of the claims are fully recognizable and determinable to one skilled in the art. The definition included in the specification provides the necessary information to properly interpret and establish the scope of the claims. The claims are clear and definite.

Applicants respectfully request that the rejection of claims 1-2, 4-8, 10-15, 17-25 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention be withdrawn.

***Claim Rejections – 35 USC § 112, first paragraph***

Claims 1-2, 4-8, 10-15 and 17-26 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. It is asserted that the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, it is asserted that Applicants do not have a possession for having any functional fragment of OX40 and composition comprising it as well as a method using the same. Applicants respectfully disagree.

As noted above, the term functional fragment is defined above. Applicants were in possession of the claimed invention at the time the application was filed.

It is well settled that the written description requirement is satisfied if the claimed composition is defined by a combination of structure and function. There is no doubt that the structure of a functional fragment is defined. The meaning of the term fragment is well known and unambiguous. One skilled in the art can readily recognize a compound having this structure. Likewise, there is no doubt that the structure of a functional fragment is defined. One skilled in the art can readily recognize a compound having this function. The definition sets forth the function clearly. It is not necessary that each species be listed and tested. All that is necessary is

that the specification make clear that applicant was in possession of the claimed invention at the time the application was filed. In view of the disclosure of both the structure and function of compounds of the claimed invention, it is clear that applicant was in possession of the claimed invention.

It is noted that the specification does not describe any example of a fragment of OX40 or provide any evidence of reduction to the practice. The Office asserts that the field is unpredictable and conclude that absent a detailed and particular description of a representative number, or at least a substantial number of the members of the genus of claimed fragment, the skilled artisan could not immediately recognize or distinguish members of the claimed fragment of Ox40. It is asserted that the full breadth of the claims does not meet the written description and enablement provision of 35 U.S.C. 112, first paragraph.

Applicants respectfully urge that the proper test for determining whether the claimed invention is in compliance with the written description requirement. It is well settled that the written description requirement is satisfied if the claimed composition is defined by a combination of structure and function. There is no doubt that the structure of a functional fragment is defined. The meaning of the term fragment is well known and unambiguous. One skilled in the art can readily recognize a compound having this structure. Likewise, there is no doubt that the structure of a functional fragment is defined. One skilled in the art can readily recognize a compound having this function. The definition sets forth the function clearly. It is not necessary that each species be listed and tested. All that is necessary is that the specification make clear that applicant was in possession of the claimed invention at the time the application was filed. In view of the disclosure of both the structure and function of compounds of the claimed invention, it is clear that applicant was in possession of the claimed invention.

Applicants respectfully urge that the specification contains a disclosure of sufficiently detailed, relevant identifying characteristics which is sufficient to provide clear evidence that applicant was in possession of the claimed invention. The reference to a fragment discloses the structure of the claimed invention. Coupled with the disclosure of the functional characteristics of the claimed invention, the specification provides clear evidence that Applicants were in

possession of the claimed invention at the time the application was filed. One skilled in the art would be able to determine whether a protein is a fragment of Ox40 and whether such a fragment increases the immune response induced by an immunogen when co-delivered compared to the immune response to an immunogen without co-delivery. The application is fully and completely in compliance with the written description requirement for the claimed invention.

Applicants respectfully request that the rejection of claims 1-2, 4-8, 10-15 and 17-26 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement be withdrawn

***Conclusion***

Claims 1, 2, 4-8, 10-15 and 17-32 are in condition for allowance. A notice of allowance is earnestly solicited.

The Commissioner is hereby authorized to charge any deficiencies of fees and credit of any overpayments to Deposit Account No. 50-0436.

Respectfully Submitted,

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